

Express Mail No.: EV 871034018 US  
Date of Deposit: January 31, 2008

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Attorney Docket No.: 24492-011

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PTO/SB (12-97)

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Modified Form 1449/PTO				Application Number		10/691,123	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Filing Date		October 22, 2003	
				First Named Inventor		Brand	
				Group Art Unit		1654	
				Examiner Name		Marcela M. Cordero Garcia	
				Attorney Docket Number		24492-011	
<b>U.S. PATENT DOCUMENTS</b>							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	*A12	4,421,712	12/20/83	Winstead	264	551	
	*A13	5,120,712	06/09/92	Habener	514	12	
	*A14	5,158,935	10/27/92	Nascimento et al.	514	12	
	*A15	5,362,716	11/08/94	Kmiecik et al.	514	12	
	*A16	5,424,286	06/13/95	Eng	514	2	
	*A17	5,512,549	04/30/96	Chen et al.	514	12	
	*A18	5,545,618	08/13/96	Buckley et al.	514	12	
	*A19	5,587,309	12/24/96	Rubin et al.	435	240.2	
	*A20	5,863,555	01/26/99	Heiber et al.	424	435	
	*A21	5,977,071	11/02/99	Galloway et al.	514	12	
	*A22	6,011,155	01/04/00	Villhauer	544	333	
	*A23	6,133,235	10/17/00	Galloway et al.	514	12	
	*A24	6,162,907	12/19/00	Habener	536	23.1	
	*A25	6,191,102 B1	02/20/01	DiMarchi et al.	514	2	
	*A26	6,268,343 B1	07/31/01	Knudsen et al.	514	12	
	*A27	6,413,952 B1	07/02/02	Luengo et al.	514	184	
	*A28	6,451,974 B1	09/17/02	Hansen	530	345	
	*A29	6,458,764 B1	10/01/02	Gravel et al.	514	12	
	*A30	6,458,924 B2	10/01/02	Knudsen et al.	530	324	
	*A31	6,506,724 B1	01/14/03	Hiles et al.	514	2	
	*A32	6,514,500 B1	02/04/03	Bridon et al.	424	193.1	
	*A33	6,858,576 B1	02/22/05	Young et al.	514	2	
	*A34	6,872,700 B1	03/29/05	Young et al.	514	2	
	*A35	6,902,744 B1	06/07/05	Kolterman et al.	424	489	
	*A36	6,956,026 B2	10/18/05	Beeley et al.	514	2	
	*A37	7,211,557	05/01/07	DiMarchi et al.	514	2	

U.S. PUBLISHED APPLICATION DOCUMENTS							
Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	*A38	2001/0006943 A1	07/05/01	Jensen et al.	514	12	
	*A39	2003/0083259	05/01/03	Novo Nordisk	514	12	
	*A40	2003/0119734	06/26/03	Novo Nordisk	514	12	
	*A41	2003/0083259 A1	05/01/03	Efendic et al.	514	12	
	*A42	2003/0119734 A1	06/26/03	Flink et al.	514	12	
	*A43	2003/0224983 A1	12/04/03	Nielsen	514	12	
	*A44	2005/0222221 A1	10/06/05	Demuth et al.	514	365	

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes	No
	B5	EP	0 619 322 B1	SCIOS INC.	10/12/94		
	B6	EP	0 699 686 B1	ELI LILLY & CO.	03/06/96		
	B7	EP	0 708 179 B1	ELI LILLY & CO.	04/24/96		
	B8	EP	0 869 135 A1	ELI LILLY & CO.	10/07/98		
	B9	WO	87/06941	GENERAL HOSPITAL CORPORATION	11/19/87		
	B10	WO	90/05185	L'UNIVERSITE DE L'ETAT A LIEGE	05/17/90	Abstract only	
	B11	WO	90/11296	GENERAL HOSPITAL CORPORATION	10/04/90		
	B12	WO	91/11457	BUCKLEY ET AL.	08/08/91		
	B13	WO	93/18786	NOVO NORDISK	09/30/93		
	B14	WO	93/19175	THORENS, B.	09/30/93		
	B15	WO	93/25579	PFIZER INC.	12/23/93		
	B16	WO	95/31214	LONDON HEALTH SCIENCES	11/23/95		
	B17	WO	97/40832	HANS-KNOLL INSTITUT	11/06/97		
	B18	WO	98/08871	NOVO NORDISK	03/05/98		
	B19	WO	99/38501	TUFTS COLLEGE	08/05/99		
	B20	WO	99/43341	NOVO NORDISK	09/02/99		
	B21	WO	99/43705	NOVO NORDISK	09/02/99		
	B22	WO	99/43706	NOVO NORDISK	09/02/99		
	B23	WO	99/43707	NOVO NORDISK	09/02/99		
	B24	WO	99/43708	NOVO NORDISK	09/02/99		
	B25	WO	99/046272	FONDATECH BENELUX	09/16/99		
	B26	WO	99/61431	PROBIODRUG	12/02/99	Abstract only	
	B27	WO	99/67278	PROBIODRUG	12/29/99	Abstract only	
	B28	WO	99/67279	PROBIODRUG	12/29/99	Abstract only	
	B29	WO	00/07617	NOVO NORDISK	02/17/00		
	B30	WO	00/42026	NOVO NORDISK	07/20/00		

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes	No
	B31	WO	00/66629	AMYLIN PHARMACEUTICALS	11/09/00		
	B32	WO	01/04156 A1	ZEALAND PHARMACEUTICALS	01/18/01		
	B33	WO	01/98331 A2	ELI LILLY & CO.	12/27/01		
	B34	WO	02/12452 A2	CURIS INC.	02/14/02		
	B35	WO	02/46227 A2	ELI LILLY & CO.	06/13/02		
	B36	WO	03/014318 A2	GENZYME CORPORATION	02/20/03		
	B37	WO	03/033671 A2	BRISTOL-MYERS SQUIBB	04/24/03		
	B38	WO	04/005342 A1	ZEALAND PHARMACEUTICALS	01/15/04		
	B39	WO	07/041833 A1	WARATAH PHARMACEUTICALS	04/19/07		
	B40	WO	07/062531 A1	WARATAH PHARMACEUTICALS	06/07/07		
	B41	WO	07/095737 A1	WARATAH PHARMACEUTICALS	08/30/07		
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS							
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.					
	C122	Abe et al., "First Synthesis and Determination of the Absolute Configuration of Sulphostin, a Novel Inhibitor of Dipeptidyl Peptidase IV", <i>J Nat Prod</i> , 67:999-1004 (2004)					
	C123	Ahmed et al., "High and Low Affinity Receptors Mediate Growth Effects of Gastrin and Gastrin-Gly on DLD-1 Human Colonic Carcinoma Cells", <i>FEBS Letters</i> , 556:199-203 (2004)					
	C124	Ahren B., "Beta-Cell expression of a dominant-negative HNF-1 $\alpha$ compromises the ability of inhibition of dipeptidyl peptidase-4 to elicit a long-term augmentation of insulin secreted in mice", <i>Euro J of Pharmacology</i> , 521:164-168 (2005)					
	C125	Ahren et al., "Inhibition of Dipeptidyl Peptidase IV Improves Metabolic Control Over a 4-Week Study Period in Type 2 Diabetes", <i>Diabetes Care</i> , 25(5):869-875 (2002)					
	C126	Ahren et al., "Inhibition of Dipeptidyl Peptidase-4 Reduces Glycemia, Sustains Insulin Levels, and Reduces Glucagon Levels in Type 2 Diabetes", <i>J Clin Endocrinol Metab</i> , 89:2078-2084 (2004)					
	C127	Baggio et al., "Therapeutic approaches to preserve islet mass in type 2 diabetes", <i>Annual Review of Medicine</i> , 57:265-281 (2006)					
	C128	Bonner-Weir et al., "In vitro cultivation of human islets from expanded ductal tissue", <i>PNAS</i> , 97(14): 7999-8004 (2000)					
	C129	Brand et al., "Prolonged Efficacy of Islet Neogenesis Therapy with Gastrin and TGF $\alpha$ in Mature Rats with Preexisting Diabetes", <i>Diabetes</i> , 50(Suppl 2):A338 (Abstract) (2001)					
	C130	Caldwell et al., "Fluoropyrrolidine amides as dipeptidyl peptidase IV inhibitors", <i>Bioorg Med Chem Lett</i> , 14:1265-1268 (2004)					
	C131	Chatenoud L., "Restoration of Self-Tolerance Is a Feasible Approach to Control Ongoing Beta-Cell Specific Autoreactivity: Its Relevance for Treatment in Established Diabetes and Islet Transplantation", <i>Diabetologia</i> , 44:521-536 (2001)					
	C132	Chatenoud et al., "Anti-CD3 Antibody Induces Long-Term Remission of Overt Autoimmunity in Nonobese Diabetic Mice", <i>Proc Natl Acad Sci U S A</i> , 91:123-127 (1994)					
	C133	Chepurny et al., "Over-expression of the glucagon-like peptide-1 receptor on INS-1 cells confers autocrine stimulation of insulin gene promoter activity: a strategy for production of pancreatic $\beta$ -cell lines for use in transplantation", <i>Cell &amp; Tissue Research</i> , 307(2):191-201 (2002)					
	C134	Chou et al., "A Radioimmunoassay for LY315902, an Analog of Glucagon-Like Insulinotropic Peptide, and Its Application in the Study of Canine Pharmacokinetics", <i>J. Pharm. Sci.</i> , 86(7):768-773 (1997)					

FOREIGN PATENT DOCUMENTS					
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	C135	Deacon et al., "Dipeptidyl Peptidase IV Inhibition Potentiates the Insulinotropic Effect of Glucagon-Like Peptide 1 in the Anesthetized Pig", <i>Diabetes</i> , 47: 764-769 (1998)			
	C136	Drucker, D.J., "Glucagon-Like Peptides: Regulators of Cell Proliferation, Differentiation, and Apoptosis", <i>Molecular Endocrinology</i> , 17(2):161-171 (2003)			
	C137	Edmondson et al., "Potent and selective proline derived dipeptidyl peptidase IV inhibitors", <i>Bioorg Med Chem Lett</i> , 14:5151-5155 (2004)			
	C138	Garcia-Ocana et al., "Transgenic Overexpression of Hepatocyte Growth Factor in the Beta-Cell Markedly Improves Islet Function and Islet Transplant Outcomes in Mice", <i>Diabetes</i> , 50:2752-2762 (2001)			
	C139	Gmyr et al., "Adult human cytokeratin 19-positive cells reexpress insulin promoter factor 1 in vitro: further evidence for pluripotent pancreatic stem cells in humans", <i>Diabetes</i> , 49(10):1671-1680 (2000)			
	C140	Holst, J.J., "Therapy of type 2 diabetes mellitus based on the actions of glucagon-like peptide-1", <i>Diabetes Metab Res Rev</i> , 18:430-441 (2002)			
	C141	Kieffer et al., "Degradation of Glucose-Dependent Insulinotropic Polypeptide and Truncated Glucagon-Like Peptide 1 in Vitro and in Vivo by Dipeptidyl Peptidase IV", <i>Endocrinology</i> , 136(8):3585-3596 (1995)			
	C142	Korc, M.J., "Islet Growth Factors: Curing Diabetes and Preventing Chronic Pancreatitis?", <i>Clin. Invest.</i> , 92:1113-1114 (1993)			
	C143	Lankas et al., "Dipeptidyl peptidase IV inhibition for the treatment of type 2 diabetes: potential importance of selectivity over dipeptidyl peptidases 8 and 9", <i>Diabetes</i> , 54:2988-2994 (2005)			
	C144	Lefebvre et al., "Culture of Adult Human Islet Preparations With Hepatocyte Growth Factor and 804G Matrix Is Mitogenic for Duct Cells but Not for Beta-Cells", <i>Diabetes</i> , 47: 134-137 (1998)			
	C145	McIntosh et al., "Applications of Dipeptidyl-Peptidase IV Inhibitors in Diabetes Mellitus", <i>Int J of Biochemistry &amp; Cell Biology</i> , 38:860-872 (2006)			
	C146	Mentlein et al., "Dipeptidyl-Peptidase IV Hydrolyses Gastric Inhibitory Polypeptide, Glucagon-Like Peptide-1(7-36)Amide, Peptide Histidine Methionine and Is Responsible for Their Degradation in Human Serum", <i>Eur J Biochem</i> , 214:829-835 (1993)			
	C147	Moller, D.E., "New Drug Targets for Type 2 Diabetes and the Metabolic Syndrome", <i>Nature</i> , 414:821-827 (2001)			
	C148	Nauck, M.A., "Glucagon-like peptide 1 (GLP-1): a potent gut hormone with a possible therapeutic perspective", <i>Acta Diabetol</i> , 35:117-129 (1998)			
	C149	Otonkoski et al., "Nicotinamide and Sodium Butyrate Have Potent Synergistic Effects on Fetal Porcine b Cell Differentiation", <i>Diabetologia</i> , 39(Supple 1):(Abstract 232) (1996)			
	C150	Patel et al., "Treatment of non-insulin-dependent diabetes mellitus", <i>Expert Opinion Investig Drugs</i> , 12(4):623-633 (2003)			
	C151	Pedersen et al., "Reactivity of the Thiol Group in Human and Bovine Albumin at pH 3 - 9, as Measured by Exchange with 2,2'-Dithiodipyridine", <i>Eur. J. Biochem.</i> , 106:291-295 (1980)			
	C152	Pederson et al., "Improved Glucose Tolerance in Zucker Fatty Rats by Oral Administration of the Dipeptidyl Peptidase IV Inhibitor Isoleucine Thiazolidide", <i>Diabetes</i> , 47:1253-1258 (1998)			
	C153	Peters et al., "Aminomethylpyridines as DPP-IV inhibitors", <i>Bioorg Med Chem Lett</i> , 14:3579-3580 (2004)			
	C154	Sandgren et al., "Overexpression of TGF $\alpha$ in Transgenic Mice: Induction of Epithelial Hyperplasia, pancreatic Metaplasia and Carcinoma of the Breast", <i>Cell</i> , 61:1121-1135 (1990)			
	C155	Sharp et al., "Transforming growth factor alpha disrupts the normal program of cellular differentiation in the gastric mucosa of transgenic mice", <i>Development</i> , 121:149-161 (1995)			

FOREIGN PATENT DOCUMENTS					
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	C156	Sjoholm A., "Diabetes mellitus and Impaired Pancreatic Beta-cell proliferation", <i>Journal of Internal Medicine</i> , 239(3):211-220 (1996)			
	C157	Stoffers et al., "Early-Onset Type-II Diabetes Mellitus (MODY4) Linked to IPF1", <i>Nat Genet</i> , 17:138-139 (1997)			
	C158	"Transition Therapeutics Confirms Effectiveness of Islet Neogenesis Therapy in Reducing Diabetic Symptoms", Transition Therapeutics Press Release, April 17, 2002			
	C159	"Transition Therapeutics Inc. Receives Approval to Initiate Phase I Clinical Trial for Islet Neogenesis Therapy", Transition Therapeutics Press Release, September 20, 2002			
	C160	"Transition Therapeutics' I.N.T.™ Treatment Stimulates Regeneration of Human Insulin-Producing Cells", Transition Therapeutics Press Release, September 26, 2002			
	C161	"Transition Therapeutics' I.N.T.™ Treatment Increases Survival", Transition Therapeutics Press Release, September 27, 2002			
	C162	Veves et al., "Can VEGF Reverse Diabetic Neuropathy in Human Subjects?", <i>J Clin Invest</i> , 107:1215-1218 (2001)			
	C163	Villhauer et al., "1-[2-[(5-Cyanopyridin-2-yl)amino]ethylamino]acetyl-2-(S)-pyrrolidinecarbonitrile: a potent, selective, and orally bioavailable dipeptidyl peptidase IV inhibitor with antihyperglycemic properties", <i>J Med Chem</i> , 45:2362-2365 (2002)			
	C164	Villhauer et al., "1-[[[3-hydroxy-1-adamantyl]amino]acetyl]-2-cyano-(S)-pyrrolidine: a potent, selective, and orally bioavailable dipeptidyl peptidase IV inhibitor with antihyperglycemic properties", <i>J Med Chem</i> , 46:2774-2789 (2003)			
	C165	Von Herrath, M., "EI-INT Transition Therapeutics/Novo Nordisk", <i>Current Opinion Investig Drugs</i> , 6(10):1037-1042 (2005)			

\* By the waiver of 37 CFR 1.98(a)(2)(ii) copies of the U.S. Patents A12-A37 and U.S. Published Applications A38-A44 are not submitted.

Examiner Signature		Date Considered	
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